

Application No. 10/820,430
Amendment Dated 5/15/2007
Reply to Office Action of 12/15/2006

AMENDMENTS TO THE DRAWINGS

The two attached sheets of drawings include changes to Figs. 4 and 5. These replacement sheets, which include Figs. 4 and 5, replace the original sheets including Figs. 4 and 5. The brightness of the images in Figs. 4 and 5 has been increased. In addition, textual annotations overlying the brightened images have been revised for improved readability.

Attachment: Two Replacement Drawing Sheets

REMARKS/ARGUMENTS

By this Amendment, Figs. 4 and 5 are amended. Claims 1-47 are pending, with claims 15-47 being withdrawn from consideration pursuant to a restriction requirement.

Drawing Objection

The objection to the darkness of Figs. 4 and 5 is obviated by the drawing corrections made by this Amendment. Accordingly, reconsideration and withdrawal of the drawing objection are respectfully requested.

Information Disclosure Statement

Applicant respectfully submits that submission of an IDS citing the Kruse reference again is unnecessary as the Examiner has already made record consideration of the reference, has initiated and amended the original IDS to include the full citation of Kruse and has fully cited Kruse on her Form PTO-892.

Claim Objections

Claims 4 and 6 are objected to because they allegedly encompass non-elected subject matter. This objection is respectfully traversed.

The August 28, 2006 restriction requirement grouped claims 4 and 6 in Group I, which comprised claims drawn to isolated pluripotent stem cells from exocrine glandular tissue. In addition, Applicant was required to elect a species of exocrine glandular tissue from which the cell are obtained. Applicant elected Group I and acinar tissue from the pancreas as the species.

Claims 4 and 6 are within the elected group, and are generic to the elected species since they are not limited to the elected species. The fact that these claims encompass non-elected species as well as the elected species is not a cause for any objection. Claims generic to an

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elected species need not be canceled in response to an election of species requirement, as suggested by the following passage from MPEP § 809.02(a):

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

The foregoing passage would be illogical if claims generic to a species election had to be canceled or amended to delete non-elected species within those generic claims.

Accordingly, reconsideration and withdrawal of the claim objection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for isolated pluripotent adult stem cells from any species of vertebrate obtained from any exocrine gland tissue, wherein said pluripotent adult stem cells differentiate into any cell type. This rejection is respectfully traversed.

It is submitted that there is clear guidance in the present specification for the skilled artisan which steps are necessary to obtain pluripotent adult stem cells from different exocrine glands and different species. It is correct that the Examples specifically disclose only the isolation of stem cells from two species, namely human and rat, and from two tissue sources, namely acinar tissue of the pancreas and exocrine tissues (acinar tissue and tubular tissue) of the parotid gland (Example 3). However, as noted by Dr. Kruse in his attached Rule 132 Declaration, a person reasonably skilled in the art would have been enabled by the original disclosure to isolate IPAS cells from a variety of cell types from a variety of organisms without undue experimentation. The Declaration describes how experimental protocols described in the

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application were used to prepare IPAS cells from four different organs of fourteen different species of animals. This evidence is sufficient to establish that the full scope of the claims is enabled by the original disclosure.

Accordingly, reconsideration and withdrawal of the enablement rejection are respectfully requested.

Claim rejections under 35 U.S.C. § 102

Claims 1-14 stand rejected as allegedly being anticipated under 35 U.S.C. § 102(b) by any one of Schneider et al., Apte et al. or Bachem et al. These rejections are respectfully traversed.

According to the Examiner, each of the cited documents Schneider et al., Apte et al. and Bachem et al. anticipates the claimed subject matter, because the “pancreatic stellate-like cells” (PSLCs) described in Kruse et al. (2004, Discussion section, first paragraph) are said to “correspond” to the “pancreatic stellate cells” (PSCs) disclosed in said references. The Examiner therefore concludes that both kind of cells are identical. However, the term “correspond” merely indicates that both cell types exhibit similar morphological characteristics but does not acknowledge or suggest that both cell types are identical. Specifically, with respect to the cells described by Bachem et al., at least one important difference, namely a lack of the capability for unlimited division and stable proliferation, has been explicitly identified by Kruse et al. Therefore, the term “correspond”, which also has been used by Kruse with respect to the cells of Bachem et al., cannot be construed as meaning “identical”.

Actually, none of these references teaches that characteristics of adult pluripotent stem cells, such as a very broad differentiation spectrum and unlimited ability for self-renewal, have

been observed with these PSCs. The Examiner concedes this fact but takes the position that in a case where claimed products and prior art products are essentially the same or produced by identical or essentially identical processes, the burden of proof that the prior art products do not inherently possess the characteristics of the claimed product may lay on the applicant. In the present case, however, the methods of preparation are not the same. According to Bachem et al., the PSCs grew out from tissue blocks, whereas the methods according to Schneider et al. and Apte et al. involve a step of density gradient centrifugation. In this step, other cells and tissue components are separated from the cells of interest which were subsequently plated on culture dishes. It is well conceivable that this centrifugation step removes either the actual progenitor stem cells or important factors or helper cells which might be required to induce the proliferation or generation of stem cells.

In contrast to this, the present method for isolation of the primary exocrine cells is very gentle (compare original claims 19 and 20) and does not involve any centrifugation steps. Therefore, in view of the different methods of preparation and the different properties reported for both cell types, it appears that there is at least a *prima facie* evidence that both cell types are actually different and, thus, the burden of proof for the opposite should remain with the PTO.

It is further noted that present claim 1 relates to isolated pluripotent stem cells. According to the present invention, these stem cells are obtained by multiple cultivation steps and passages in the course of which the differentiated cells gradually are removed and only the pluripotent stem cells finally remain. Even if the cell cultures of Schneider et al. or Apte et al. should have comprised a minority of stem cells which remained unnoticed, such cell cultures would not anticipate the claimed subject matter.

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For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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Please charge or credit our
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